

HPV Vaccination: Public Health Education and Acceptability Issues

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Objectives



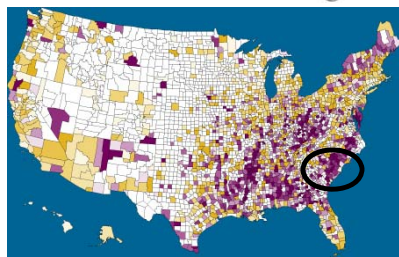
By the end of the session, participants will be able to:

- Describe the first vaccine for some types of HPV (GARDASIL®);
- Identify challenges related to acceptability and uptake of HPV vaccines; and
- Discuss current efforts to promote informed decision making of HPV vaccines.

Public Health Problem: Excess Cervical Cancer Mortality




*What's
wrong with
this
picture?*




Source: Freeman HP, Wingrove BK. Excess cervical cancer mortality: A marker for low access to health care in poor communities. Rockville, MD: National Cancer Institute, Center to Reduce Cancer Health Disparities; 2005. Report: NIH Pub. No. 05-5282.

From Research to Practice




- High-risk (oncogenic or cancer causing) types of genital HPV identified as main factor in development of cervical cancer (and other types of cancer) [1980s but as early as 1970s by zur Hausen]
- Introduction of HPV DNA test to determine presence/absence of high-risk HPV in abnormal Pap tests [1990s]
 - Introduction of HPV DNA testing as primary screening method for females aged 30 and older [2000s]
- **Introduction of vaccines for some types of genital HPV [2000s]**
 - **Gardasil® (Licensed by US FDA)**
 - **Cervarix™ (In review by the US FDA)**

HPV Vaccination




- **GARDASIL® (Merck & Co.)**
 - First preventive vaccine for four types of genital HPV (6, 11, 16, 18)
 - Two high-risk types: 16, 18
 - Linked to cervical dysplasia and cervical cancer
 - Two low-risk types: 6, 11
 - Cause genital warts

HPV Vaccination




- **GARDASIL® (Merck & Co.)**
 - FDA licensed/approved for females, aged 9-26 (June 2006)
 - See: U.S. Food and Drug Administration Office of Oncology Drug Products: FDA Licenses Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine (Gardasil) for the Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus. July 20, 2006. Available at: <http://www.fda.gov/cder/offices/oodp/whatsnew/gardasil.htm>.
 - CDC recommended for females 11-12, but can get as early as 9 and up to age 26
 - See: Centers for Disease Control and Prevention. Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices. *Morbidity and Mortality Weekly Report*. March 12, 2007;56:1-24.

HPV Vaccination




- GARDASIL® (Merck & Co.)
 - Three shots (0, 2, 6 months)
 - Cost: about \$120-140/dose plus office and administration fees
 - **Note: This is only an estimate of cost. Cost varies by location due to differences in office and administration fees and other factors.**
 - Duration of protection (how long the vaccine lasts) continues to be studied

HPV Vaccination




- GARDASIL® (Merck & Co.)
 - Effective (thus far)
 - Clinical trials in females (ages 16-26 years) have demonstrated 100% efficacy in preventing cervical pre-cancers caused by the targeted HPV types
 - Nearly 100% effective in preventing vulvar and vaginal pre-cancers and genital warts caused by the targeted HPV types
 - No therapeutic effect on HPV-related disease, i.e. GARDASIL® does not treat disease due to HPV types already acquired
 - Safe (thus far)
 - Reissued prescribing information in September 2008 to document adverse events

HPV Vaccination




- GARDASIL® (Merck & Co.)
 - Vaccines will **not** replace cervical cancer screening (but will likely change it in the future)
 - Uptake has varied
 - Concerns about access and acceptability persist

HPV Vaccination




- Cervarix™ (GlaxoSmithKline)
 - **NOT LICENSED** by US FDA (application pending), but licensed in other countries
- Bivalent prophylactic vaccine (16, 18)
 - GARDASIL®: Quadrivalent (6, 11, 16, 18)
- Two shots
 - GARDASIL®: Three shots
- Adjuvant differences (AS04)
 - GARDASIL®: Aluminum

Vaccine Acceptability



Age: Why so young?



- Current vaccine (GARDASIL®) is preventive, not therapeutic, so vaccination prior to exposure is key
 - Skin-to-skin transmission in the anogenital region (intercourse NOT necessary)
 - Nearly half (48%) of high school students in the U.S. have ever had sex
 - Median age of first sex in the U.S. is 16.9 for males and 17.4 for females
 - 9.1 million STIs diagnosed among 15-24 year olds in the U.S. 2000
 - HPV is most common (51% of new infections)
- Immune response of GARDASIL® is robust in adolescents

Source: Kaiser Family Foundation, Sexual health of adolescents and young adults in the United States. 2008 Sep. Available at: http://www.kff.org/womenshealth/upload/3040_04.pdf; and Weinstock et al., (2004)

Age: Why so young?

HPV & Adolescents Clinic-based Study in SC (2006)

50% of females have had sexual intercourse


43% of White youth and 66% of Black youth have had sexual intercourse

Source: CDC BRFSS, SC Data, 2005

About 75% of participants had ever had sexual intercourse.

Females who took part in the study reported that they had ever had sex more often than youth who completed the South Carolina statewide survey.

Source: Brandt HM, Bynum SA, Wright MS, et al. Psychosocial, Educational, and Behavioral Factors Related to HPV among Adolescent Girls and Young Women. Unpublished Data



Age: Why so young?

HPV & Adolescents Clinic-based Study in SC (2006)

60% of females used a condom during their last sexual intercourse


63% of White youth and 72% of Black youth used a condom during their last sexual intercourse

Source: CDC BRFSS, SC Data, 2005

About 55% of participants used a condom during their last sexual intercourse

Females who took part in the study reported that they were slightly less likely to have used a condom during last sex than youth who completed the South Carolina statewide survey.


Source: Brandt HM, Bynum SA, Wright MS, et al. Psychosocial, Educational, and Behavioral Factors Related to HPV among Adolescent Girls and Young Women. Unpublished Data




Gender: Why only females?

- Focus on prevention of cervical disease was prioritized
- Past history of gender-neutral vaccinations (e.g., Herpes, HIV)
- *Recommendations for males possible in future*
 - Males as “carriers” of HPV but also at risk for HPV-associated diseases

Source: Brandt HM, Bynum SA, Wright MS, et al. Psychosocial, Educational, and Behavioral Factors Related to HPV among Adolescent Girls and Young Women. Unpublished Data



Barriers to Getting HPV Vaccine* in South Carolina




- **What do you think would stop you from getting the HPV vaccine?**
 - **How much it costs to get the vaccine (55%)**
 - You don't think it will work (22%)
 - Fear of needles (13%)
 - Fear of vaccines (11%)
 - Going back for two shots over 4-6 months (9%)
 - No time off to go to clinic (8%)
 - Transportation to the clinic (7%)
 - What people would think of you if you got it (2%)

*Asked prior to clinical availability of vaccine; among participants who have ever heard of HPV

Source: Brandt HM, Sharpe PA, McCree DH, Wright MS, Davis J, Hutto BE. HPV vaccine acceptance in a clinic-based sample of women in the rural south. Submitted to: Am J Hlth Educ (In Review)

Barriers to Getting HPV Vaccine* in South Carolina




- **What is the main reason you would NOT have her get it [HPV vaccine] ?**
 - Safety concerns about the vaccine (side effects) (20.0%)
 - Not sexually active (6.1%)
 - Might promote sexual activity (3.1%)
 - I don't know where to get it (1.9%)
 - Too expensive (1.4%)
 - Other (57.5%)
 - Top three "other" reasons:
 - Respondent does not know enough about it (17.8%)
 - Need more information (5.8%)
 - Respondent needs to do more research on vaccine/side effects, 3.6%


*Asked after clinical availability of vaccine; among participants who have ever heard of HPV and would not have daughter vaccinated (n=360 out of 1,029 total respondents)

Source: Brandt HM, Sharpe PA, Bellinger J, Hardin J. A Population-Based HPV Survey of Women in South Carolina: 1R15CA125600-01 (PI: Brandt); Unpublished Findings

Access to Vaccination




Access to Vaccination



- Nearly 20% of South Carolinians are uninsured (47 million uninsured in U.S.)
 - Uninsured and underinsured women are less likely to be screened and more likely to be diagnosed at advanced stages of cervical cancer
- Access to HPV vaccines, currently Gardasil®
 - Private physicians
 - Vaccines for Children program
 - Merck Patient Assistance Program
 - Community health centers


Sources: DeNavas-Walt, Carmen, Bernadette D. Proctor, and Cheryl H. Lee. U.S. Census Bureau. Current Population Reports, P60-229. Income, Poverty, and Health Insurance Coverage in the United States: 2004. U.S. Government Printing Office, Washington, DC, 2005.; American Medical Association. Voice for the Uninsured. Available at: <http://www.voicefortheuninsured.org>. Retrieved October 1, 2007.; United Health Foundation. America's Health Rankings, 2006. Available at: <http://www.unitedhealthfoundation.org>. Retrieved October 1, 2007.

Access to Vaccination



- Vaccines for Children Program
 - DHEC offers free childhood and adolescent immunizations to eligible persons through a program called the South Carolina Vaccine Assurance For All Children (VAFAC) Immunization Partnership.
 - Contact numbers for county public health departments can be found at <http://www.scdhec.gov/health/county.htm> or contact the DHEC Immunization Division at 1-800-277-4687.
- Merck Patient Assistance Program:
<http://www.merck.com/merckhelps/>

SC VAFAC's Vaccine Supply Policy



Current Adolescent Vaccine Funding Sources in South Carolina

Funding Source	Percentage
VFC	58%
Fed 317	30%
State	8%
Private	4%

GARDASIL® Availability

VFC


- Medicaid
- Uninsured
- American Indian/Alaska Native
- Underinsured if served in a FQHC (CHC/RHC)

Federal 317 & State

- Underinsured

(but not appropriated for GARDASIL® so far)

Impact of Two-tiered Vaccine Policy



To access GARDASIL®, underinsured adolescents will have to:

- (1) Pay out-of-pocket for vaccine in their medical homes;
- (2) Go to a federally qualified community health center or rural health center;
- (3) CHC or RHC delegate authority to health department.


Federally-qualified health centers:

- 126 of 601 (21%) VAFAC practices
- Serve 11% of total VAFAC patient encounters

Not the case for other vaccines

Source: Jesse Greene, MSN, RN, SC DHEC, Director, Immunization Division


Impact of Gaps in Financing



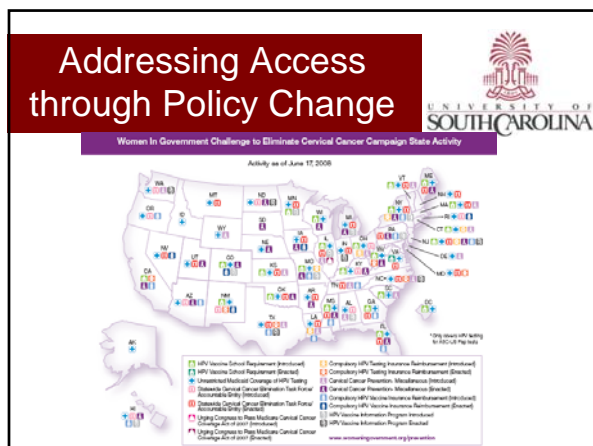
- Current vaccine financing system in US has resulted in gaps
- Availability of financing impacts immunization rates
- Additional strategies are needed to ensure financial coverage for all vaccines, particularly new vaccines, among underinsured children

Source: Lee GM et al. Gaps in vaccine financing for underinsured children in the United States. JAMA. 2007 Aug;298(6): 638-643.

Addressing Access through Policy Change



- South Carolina House Bill 3136
 - 7th grade girls; 2009-2010 school year
 - Timeline
 - December 13, 2006: Prefiled for 117th Session, 2007-2008
 - January 9, 2007: Introduced and read for first time
 - March 21, 2007: Passed Health and Environmental Affairs Subcommittee (3)
 - April 12, 2007: Passed 3M: Medical, Military, Public and Municipal Affairs Committee (18)
 - **April 18, 2007: Bill tabled (by Rep. Brady)**



Uptake of GARDASIL®

UNIVERSITY OF SOUTH CAROLINA

- Predicted uptake of CERVARIX™ in Australia has ranged from 67-90%
- Predicted uptake of HPV vaccines in UK has ranged from 70-80%
 - Recent study has shown actual uptake in Manchester to be in this range (first dose=70.6%; second dose=68.5%)

Sources: Smith MA et al. The predicted impact of vaccination on human papillomavirus infections in Australia. Int J Cancer 2008;123:1854-1863; Brabin L et al. Future acceptance of adolescent human papillomavirus vaccination: a survey of parental attitudes. Vaccine 2006;24:3087-94; and Marlow LAV et al. Parental attitudes to pre-pubertal HPV vaccination. Vaccine 2007;25:1945-52; Brabin L et al. Uptake of first two doses of human papillomavirus vaccine by adolescent schoolgirls in Manchester: prospective cohort study. BMJ. 2008;336:1056-1058.

Uptake of GARDASIL®

UNIVERSITY OF SOUTH CAROLINA

- 25% had at least one of the GARDASIL® shots
- Results based on phone survey of 3,000 female teens, ages 13 to 17
- Many families are cautious about vaccine's safety

Uptake of GARDASIL®



- Self-report among participants who had a daughter(s) between age 9 and 18:
 - **Has she had the HPV vaccine?**
 - Yes (19.9%)
 - No (73.3%)

*Asked after clinical availability of vaccine; among participants who had a daughter(s) between age 9 and 18 (n=176 out of 1,029 total respondents)
Source: Brandt HM, Sharpe PA, Bellinger J, Hardin J. A Population-Based HPV Survey of Women in South Carolina; 1R15CA125600-01 (PI: Brandt); Unpublished Findings

Uptake of GARDASIL®



- GARDASIL® data requested from SC DHEC (pending request)
- Predicted uptake of new vaccines in SC ranges from 0-25%
- Rates of uptake of other vaccines
 - Second dose MMR = 97.6%
 - Hepatitis B series = 96.1%

Source: Jesse Greene, MSN, RN, SC DHEC, Director, Immunization Division


How can we ensure access for ALL people who want to get the HPV vaccine in South Carolina?

How can we make sure that disparities in HPV vaccine uptake do not INCREASE disease disparities?

Behavioral Disinhibition




Behavioral Disinhibition



- Concern that HPV vaccine will lead to increased sexual risk
- May influence implementation
 - Newspaper media coverage cite as barrier
 - Parents may be less likely to vaccinate children
 - Pediatricians may be less likely to recommend
- Possibility of behavioral disinhibition can and should be addressed

Adapted from Liddon et al.; Calloway et al., unpublished; Daley et al., unpublished; Kahn et al., 2005 J Adolesc Health; 37(5):502; and Olshen et al., 2005 J Adolesc Health 37(3): 248; Zimet et al., 2005 Arch Pediatr Adolesc Med 2005; (159):132

Behavioral Disinhibition



- An increase in unsafe behaviors in response to perceptions of safety caused by introduction of a preventive or therapeutic intervention
- Historically a concern:
 - Anesthesia for childbirth/sex
 - Penicillin for syphilis/sex
 - Needle exchange/drug use
 - Condom availability programs/sex
 - Emergency contraception/sex

Adapted from Liddon et al.; Calloway et al., unpublished; Daley et al., unpublished; Kahn et al., 2005 J Adolesc Health; 37(5):502; and Olshen et al., 2005 J Adolesc Health 37(3): 248; Zimet et al., 2005 Arch Pediatr Adolesc Med 2005; (159):132

Behavioral Disinhibition



- Unlikely sexual behavioral disinhibition will result from HPV vaccine:
 - Multiple other factors associated with adolescent sexual risk
 - Fear of STI not apparent major motivation for abstinence
 - No evidence of behavioral disinhibition in other similar fields

Adapted from Liddon et al., unpublished; Calloway et al., unpublished; Daley et al., unpublished; Kahn et al., 2005 J Adolesc Health; 37(5):502; and Olshen et al., 2005 J Adolesc Health 37(3): 248; Zimet et al., 2005 Arch Pediatr Adolesc Med 2005; (159):132

How can we ensure that this information about the lack of evidence supporting sexual disinhibition is clearly communicated to decision-makers?



Health Care Providers



Health Care Providers



- Very influential role of health care providers in vaccination uptake
- Limited knowledge of HPV among pediatricians
- Limited vaccination experience among OB/GYNs
- New adolescent vaccines
- No normally schedule adolescent preventive health visit (except for sports physicals)

Public Health Education




Public Health Education



- Very low levels of HPV knowledge
- Limited understanding of relationship of HPV and cervical cancer
- Little to no understanding of HPV testing and HPV vaccines (but interested)
- Need for improved public health educational efforts
 - Result in informed patients who can be partners in choosing appropriate follow-up care, seeking more information, and identifying sources of social support
 - Promote adherence to follow-up care, e.g., understanding relationship between abnormal Pap test result and HPV and how this places women at higher risk for cervical cancer
 - Facilitate informed decision making and access to new tools, such as HPV vaccines and HPV DNA testing

Sources: Sharpe PA, Brandt HM, McCree DH. Knowledge and beliefs about abnormal pap test results and HPV among women with high-risk HPV: results from in-depth interviews. Women Health. 2005;42(2):107-33; McCree DH, Sharpe PA, Brandt HM, Robertson R. Preferences for sources of information about abnormal Pap tests and HPV in women tested for HPV. Prev Med. 2006 Sep;43(3):165-70.


Public Health Education



- Influence of technology
 - User-generated content on Internet
 - Post and retrieve content
 - YouTube (146 videoclips)
 - 75% portrayed vaccination in positive manner
 - Accuracy of information was not evaluated
 - **Inaccuracies and misinformation**
 - **Recognition by health care providers and public health professionals of technology in public health education**


Source: Ache KA, Wallace LS. Human papillomavirus vaccination coverage on YouTube. Am J Prev Med. 2008 Oct;35(4):389-92.

Public Health Education






- Keep it **short**
 - Focus on 3-4 messages that you want the people to remember
- Keep it **simple**
 - “Break it down” to make sure that people understand
 - Use medical terms but provide plain language explanations
- Use written materials to **reinforce** messages
- **Provide direction** to appropriate and accurate resources for people interested in learning more
 - 1-800-ACS-2345 // 1-800-4CANCER
- Make sure information is **culturally- and language-appropriate and accurate**

Resources





- CDC: Pre-teen Vaccine Campaign Posters
 - <http://www.cdc.gov/vaccines/Spec-grps/preteens-adol/07gallery/posters.htm>
 - <http://www.cdc.gov/vaccines/Spec-grps/preteens-adol/07gallery/flyers.htm#qahpv>






Resources


- CDC: HPV educational materials and messages for women (partially informed by results of SC study)
 - Go to: <http://www.cdc.gov/std/hpv/default.htm>
- CDC: HPV educational materials and messages for health care providers (partially informed by results of SC study)
 - Go to: <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-hcp.htm>







Knowledge may be powerful but it is only as powerful as how we act upon what we know.



How can we make sure that ALL South Carolinians know and understand about cervical cancer, HPV, and HPV vaccines?

When is the right time for us to start providing this information?

What are the best ways to provide this information?

Summary



Implementation Challenges



- Challenges delivering the vaccine due to cost and delivery mechanisms
- Virginia is only state to enact school entry mandate
- Five states have passed laws to cover the cost of the HPV vaccine
- General vaccine safety remains a prominent concern

Source: Kaiser Family Foundation. HPV vaccine: Implementation and financing policy in the U.S. 2008 Feb. Available at: http://www.kff.org/womenshealth/upload/7602_02.pdf.


Public Outreach and Awareness



- Knowledge about HPV incidence and transmission as well as physician recommendation are important factors influencing parental acceptability
 - Only 40% of women aged 18-75 have heard of HPV and of that group, less than half know that it is associated with cervical cancer (Tiro et al., 2007)

Source: Kaiser Family Foundation. HPV vaccine: Implementation and financing policy in the U.S. 2008 Feb. Available at: http://www.kff.org/womenshealth/upload/7602_02.pdf.

Summary



- HPV vaccines present innovation in cervical cancer prevention and control
- Opportunities:
 - Providing accurate, non-industry-sponsored information in culturally- and literacy-appropriate formats
 - Promoting informed decision making among consumers
 - Facilitating equivocal access to vaccination

Contact Information



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Complete list of scientific references are available upon request.
